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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,604	12/17/2001	Chi-Yue Wu	179.7294USU	2907

7590

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EXAMINER

LEWIS, PATRICK T

ART UNIT

PAPER NUMBER

1623

DATE MAILED: 02/14/2003

3

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/023,604

Applicant(s)

WU ET AL.

Examiner

Patrick T. Lewis

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: .

DETAILED ACTION

Claim Objections

1. Applicant is advised that should claim 1 be found allowable, claims 4-7 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof; and should claims 2-3 be found allowable, claims 8-9 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-2, 4-8, and 10-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 1, applicant has failed to particularly point out the identity of the modifications to said compounds which distinctly set forth the structural core modifications or chemical moieties effectuating said derivatization. In the absence of distinct modifications or derivatizing moieties, the term "derivatives" is indefinite in all occurrences. Compounds of formula (I) are also seen to be incomplete when $m = 0$.

Art Unit: 1623

When $m = 0$, R_4 is not present resulting in a carbon atom with an incomplete valence. In the absence of an indication of R_4 being 1, 2, or 3, claims reading of compounds of formula (I) are indefinite in all occurrences.

In claim 10, the term "using" has not been defined in such a way as to reasonably apprise one of ordinary skill in the art of metes and bounds of said term. Applicant has failed to provide clear guidance as to how the saponin derivative is used in the recited method.

4. Regarding claims 11-13, applicant has failed to particularly point out the identity of the "invention" as recited in line 3 of claim 11. Applicant's failure to identify the "invention" renders the claim incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

6. Claims 1-13 are rejected under 35 U.S.C. 102(b) as being anticipated by *Konoshima Saponis Used in Traditional and Modern Medicine*, 1996, pages 86-101 (Konoshima).

Konoshima discloses saponin derivatives of formula (I) and methods for treating conditions associated with sialyltransferase as claimed by applicant. Glycosides disclosed by Konoshima corresponding to the instantly claimed saponin derivatives of formula (I) include wistariasaponin C, soyasaponin I, and soyasaponin II (page 88; compounds 4, 7, and 8). Konoshima further discloses soyasaponin I as a valuable anti-tumor-promoter when co-administered with afromosin to mice (pages 90-91).

7. Claims 1-13 are rejected under 35 U.S.C. 102(e) as being anticipated by Bombardelli et al. US Patent 6,280,777 B1 (Bombardelli).

Bombardelli discloses saponin derivatives of formula (I) and methods for treating conditions associated with sialyltransferase as claimed by applicant. Bombardelli discloses a method for treating cancer by administering to a subject in need of such treatment a therapeutically effective amount of a soya extract (column 4, lines 46-52) comprising a content of glucoside isoflavones of at least 13% by weight and a content of 0.6 to 1.5 parts by weight of group 3 soya saponins per 1 part by weight of glucoside isoflavones (column 4, lines 36-41). Saponins disclosed as having such a beneficial effect include soyasaponin I, soyasaponin II, soyasaponin III, soyasaponin IV, soyasaponin V, and soyasaponin II isomer (column 5, lines 21-54).

Conclusion

8. Claims 1-13 are pending. Claims 1-13 are rejected. No claims are allowed.

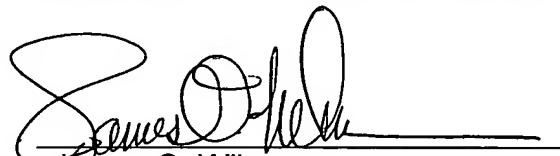
Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick T. Lewis whose telephone number is 703-305-4043. The examiner can normally be reached on M-F 10:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703-308-4624. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Patrick T. Lewis, PhD
Examiner
Art Unit 1623



James O. Wilson
Supervisory Patent Examiner
Technology Center 1600

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February 6, 2003